

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

10/509824

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 October 2003 (09.10.2003)

PCT

(10) International Publication Number
WO 03/082248 A3(51) International Patent Classification⁷: A61K 9/16, 31/7048

(21) International Application Number: PCT/IB03/01221

(22) International Filing Date: 3 April 2003 (03.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 426/DEL/2002 3 April 2002 (03.04.2002) IN

(71) Applicant (for all designated States except US): RANBAXY LABORATORIES LIMITED [IN/IN]; 19, Nehru Place, 110 019 New Delhi, Delhi (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): DABRE, Rahul [IN/IN]; 15A, Ujwal Society, Marendranagar, 440 015 Magpur (IN). NAGAPRASAD, Vishnubhotla [IN/IN]; 102, Surya Niwas Apartments, Balaji Nagar, Kukatpally, 500 072 Hyderabad (IN). MALIK, Rajiv [IN/IN]; 6-B, Pocket-B, Gangotri Enclave, Alaknanda, 110 019 New Delhi (IN).

(74) Common Representative: RANBAXY LABORATORIES LIMITED; c/o DESHMUKH, Jay R., 600 College Road East, Suite 2100, Princeton, NJ 08540 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report: 24 December 2003

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/082248 A3

(54) Title: TASTE MASKED COMPOSITIONS OF ERYTHROMYCIN A AND DERIVATIVES THEREOF

(57) **Abstract:** A pharmaceutical composition includes erythromycin A or a derivative thereof and alginic acid. The alginic acid provides taste masking of the erythromycin A or derivative. The erythromycin A derivative may be clarithromycin and the alginic acid may be one or both of alginic acid and its salt. The salt may be one or more of sodium alginate and calcium alginate. The pharmaceutical composition may further include one or more of a binder, a disintegrant, a flavoring agent, and a coating. The pharmaceutical composition also may include one or more active ingredients, including omeprazole, metronidazole, amoxicillin, rifampicin, lansoprazole, ciprofloxacin, ethambutol, and ritonavir. The erythromycin A or a derivative thereof and the one or more active ingredients may be combined in a single pharmaceutical composition.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/01221A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/16 A61K31/7048

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|----------------------------------|
| X | WO 02 17885 A (KUMAR MANOJ ;RAMPAL ASHOK (IN); RANBAXY LAB LTD (IN); RAGHUVANSHI) 7 March 2002 (2002-03-07) page 6, line 3 – line 7 page 9, line 11 – line 17 page 11 –page 12; example 2 — WO 98 56357 A (ABBOTT LAB) 17 December 1998 (1998-12-17) page 5, line 1 – line 13 page 7, line 1 – line 20 page 7 –page 8; example 1 — —/— | 1-8, 11, 14, 15, 17, 22-33 |
| X | | 1-8, 11-15, 17, 20-34 |

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the International search

29 September 2003

Date of mailing of the International search report

23/10/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Muller, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/01221

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|---|---|
| X | EP 0 635 261 A (LIPOTEC SA) 25 January 1995 (1995-01-25) page 5; example 1 page 7, line 17 - line 18 ---- | 1,3-8, 11-15, 17, 20-23, 28,30-34 |
| A | DATABASE CA 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; MASUBUCHI, AKIHIKO: "Anionic polymers for easier swallowing of bitter medication" retrieved from STN Database accession no. 138:292763 XP002255954 abstract & JP 2003 104912 A (WAKODO CO., LTD., JAPAN) 9 April 2003 (2003-04-09) ---- | 35-37 |

INTERNATIONAL SEARCH REPORTInternational Application No.
PCT/IB 03/01221**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 28-34 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 03/01221

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|------------------|--|--|
| WO 0217885 | A 07-03-2002 | AU 8432401 A EP 1315478 A2 WO 0217885 A2 US 2002081332 A1 | 13-03-2002 04-06-2003 07-03-2002 27-06-2002 |
| WO 9856357 | A 17-12-1998 | US 5705190 A WO 9856357 A1 BG 104064 A NO 996161 A SI 20108 A ,B SK 161299 A3 AT 170744 T AU 701268 B2 AU 1025297 A CA 2209714 A1 CZ 9702212 A3 DE 69600620 D1 DE 69600620 T2 DK 799028 T3 EP 0799028 A1 ES 2122810 T3 HU 9800516 A2 JP 11513406 T JP 3292732 B2 NZ 323332 A PL 321363 A1 RO 117501 B RU 2142793 C1 TR 9800777 T2 TW 429154 B WO 9722335 A1 ZA 9610110 A | 06-01-1998 17-12-1998 29-09-2000 13-12-1999 30-06-2000 16-05-2000 15-09-1998 21-01-1999 14-07-1997 26-06-1997 17-12-1997 15-10-1998 06-05-1999 07-06-1999 08-10-1997 16-12-1998 28-08-1998 16-11-1999 17-06-2002 27-04-1998 08-12-1997 30-04-2002 20-12-1999 21-07-1998 11-04-2001 26-06-1997 18-06-1997 |
| EP 0635261 | A 25-01-1995 | ES 2068762 A1 AT 178205 T DE 69417481 D1 DE 69417481 T2 DK 635261 T3 EP 0635261 A1 JP 7145044 A US 5736161 A | 16-04-1995 15-04-1999 06-05-1999 25-11-1999 18-10-1999 25-01-1995 06-06-1995 07-04-1998 |
| JP 2003104912 | A 09-04-2003 | NONE | |